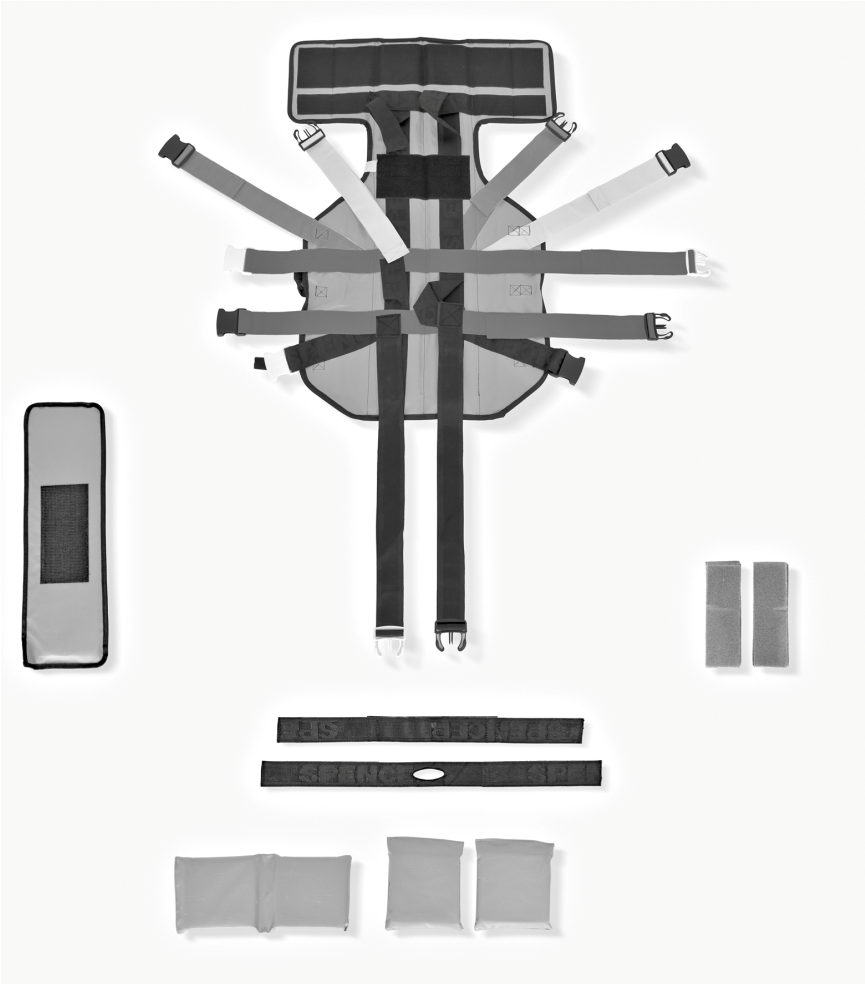
User's Manual

Spencer Spine Splint

Extrication/spine immobilization device



CE This appliance conforms with the Directive 93/42/CEE "Medical Devices"

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GmbH

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Thank you for choosing a Spencer product

1. GENERAL INFORMATION

1.1 Aim and contents

The aim of this manual is to supply all the information necessary so that the client, will not only attain adequate use of the appliance, he will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 Conservation of the instruction and maintenance manual

The instruction and maintenance manual must be kept together with the product, for the whole life of the device, inside a dedicated container and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 Symbols used

Symbol	Meaning
	General or specific warnings
	See instructions for use
LOT	Lot number
REF	Product code
CE	The product is compliant with the specifications of the Directive 93/42/CEE

1.4 Servicing request

For any information regarding the correct interpretation of the instruction manual, the use, maintenance, installation and restore of the product, please contact the Spencer Customer Care Service tel. 0039 0521 541111, fax 0039 0521 541222, e-mail service@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY. In order to facilitate the assistance service, please always indicate the lot number (LOT) shown on the label applied on the box or on the device.

1.5 Demolition

When the devices are no more suitable for being used, if they haven't been contaminated by any particular agents, they can be disposed of as normal solid waste, otherwise follow the current regulations about demolition.

1.6 Labelling

Each device has got an identifying label, positioned on the device itself and/or on the box. This label includes information about the manufacturer, the product, the CE mark, the lot number (LOT). It must never be removed or covered.

2. WARNINGS

2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the competent authorities and/or manufacturer if requested.
- Spencer Italia S.r.l. is always at your disposal to plan trainings on products.
- Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- If the instructions belong to another device and not to the device received, inform the manufacturer immediately and avoid use of the device.
- In case of any doubts about the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Do not allow untrained persons to help during the use of the device, because they could cause damage to the patient or to themselves.
- Regularly check the appliance, carry out the prescribed maintenance and respect the average life span, as indicated by the manufacturer in this user's manual.

- Before each use of device the perfect operating state of the device must be checked as specified in the instruction manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and of the user are detected, the device must be immediately removed from service and the manufacturer must be contacted.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.
- Use of the device in anyway other than described in this manual is forbidden.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with (modification, adjustment, addition, replacement). In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself; moreover CE certification and product warranty will be considered void.
- Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Handle with care.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Store and transport device in its original packaging.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- Attention: laboratory testing, post production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staffs with adequate technical formation.
- With reference to the D. Lgs. 24th February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacture as specified and within time given by the European regulations.
- In addition, both public and private operators are obliged to inform the manufacturer of any measures that should be adopted to make the steps necessary to guarantee the safety and the health of the patients and the users o any medical device.
- As a distributor or end user of products manufactured and/or marketed by Spencer Italia S.r.l., you are strictly required to have a basic knowledge of any legal requirements applying to the devices contained in this supply that are in power in the goods final destination Country (including laws and norms regarding technical specifications and/or safety requirements) and therefore you are also strictly required to have the necessary knowledge to guarantee all aspects regarding the total conformity of the products to the regulations in the relevant territory.
- Promptly notify Spencer Italia S.r.l. regarding any revisions to be made by manufacturer in order to guarantee the conformity of the product to the territory's legal specifications (including those resulting from rules and/or norms of other nature).
- Act, with all due care and diligence, and contribute to ensure conformity to general safety requirements of all devices marketed in the territory, by providing final users with all necessary information for carrying out periodical checks on their devices, as specified in the relevant user's manual.
- Actively contribute to product safety checks on products sold, by communicating any relevant risk analysis information both to the manufacturer and to any competent authorities so that the necessary action can be promptly taken.
- The distributor or final user is aware that in the event of any failure to conform to the above mentioned requirements you will be deemed fully responsible for all damages that might occur. Therefore Spencer Italia S.r.l. expressly disclaims any responsibility and/or liability for your non-compliance with the present regulatory provisions.

2.2 Specific warnings

- Establish a maintenance program and periodic testing, identifying a reference employee. The person to whom the ordinary maintenance of the device is entrusted must ensure the basic requirements foreseen by the manufacturer in the user's manual.
- All maintenance and periodic check activities must be registered and collected together with their intervention reports (see Maintenance Register) these documents have to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the competent authorities and/or manufacturer if requested.

- Use only components/spare parts and/or accessories that are original or approved by Spencer Italia S.r.l. in order to carry out any operation without causing any alteration or modification to the device, otherwise we assume no responsibility for the proper functioning or damage resulting from device to the patient or the operator and warranty and will be considered void according to the compliance to the Medical Device Directive 93/42/CEE.
- Always respect the maximum load capacity of the device, as indicated in this user's manual. Maximum load capacity means the total weight distributed according to the human anatomy. In determining the load of the total weight on the product, the operator must consider the weight of the patient, the equipment and the accessories. Moreover, the operator must consider that the overall dimensions of the patient do not reduce the functionality of the device.
- Never leave the patient unassisted on the device, because he may be injured.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- Follow the procedures approved by the Emergency Medical Service for the immobilization and transport of patients.
- Follow the procedures approved by the Emergency Medical Service for the positioning and transport of patients.
- Do not wash in a washing machine device.
- Do not use drying machines.
- Avoid contact with sharp objects.
- Do not use the device if it is pierced, torn, frayed or eccessively worn out.
- Make sure, before lifting, that the operators have a firm grip on the device.
- Avoid pulling the device on rough surfaces.
- Do not lift by crane or other mechanical lifters.

2.1 Contraindications and side effects

The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

3. DESCRIPTION OF PRODUCT

3.1 Intended use

Spencer Spine Splint is an essential and modern extrication/transport system for traumatised patients.
Particularly indicated for patient's immobilization from skull to basin when rescue operations are performed in car, the use of this device is crucial prior to loading the patient on a spine board. To obtain an effective extrication, it is necessary to optimise subsidies application times. They will be applied in this order: cervical collar, extrication device, spine board.
Trained and organized rescuers will be able to immobilize a patient correctly and extract him from any damaged vehicle in a short time. Before being able to apply the immobilization protections for vertebral column, it will be necessary to bring back the patient in aligned position. Apply therefore a cervical collar of the suitable size.

3.2 Main components

1. Thorax belts
2. Abdominal belts
3. Thigh belts
4. Rear support
5. Nape pillows
6. Forehead part
7. Chin holder
8. Transport bag

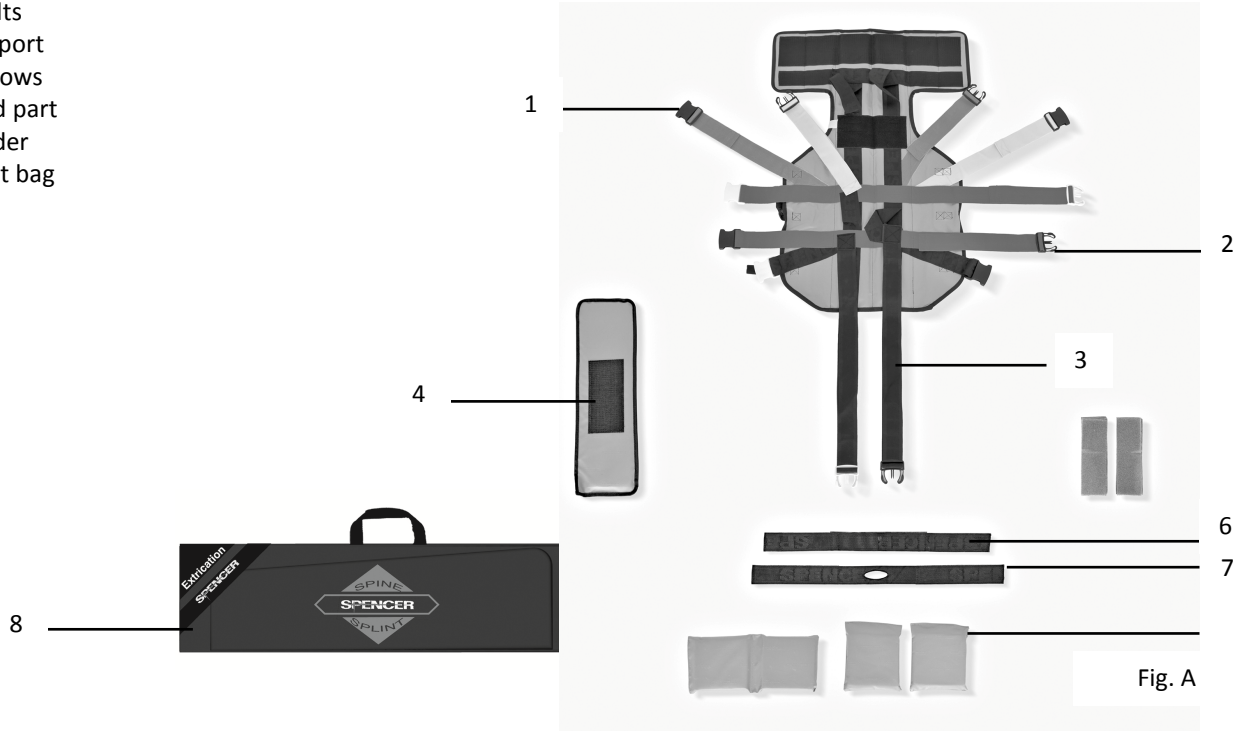

Fig. A

3.3 Models

These basic models could be modified, with reference to codes and/or descriptions without any previous notification.

SR00160A Spencer Spine Splint adult
SR00190A Spencer Spine Splint medium
SR00180A Spencer Spine Splint paediatric

3.4 Technical data

Spencer Spine Splint	Adult (SR00160A)	Medium (SR00190A)	Paediatric (SR00180A)
Dimensions inside the bag (mm)	930 x 210 x 70	830 x 230 x 70	750 x 210 x 70
Dimensions open (mm)	850 x 580 x 15	750 x 500 x 15	680 x 440 x 15
Weight with bag and accessories (kg)	3,3		2,5

3.5 Reference standards

Reference	Title of document
MDD 93/42/CEE	European Directive about Medical Devices
MDD 2007/47/CEE	Modifications to 90/385/CEE Directive about active implants, Directive 93/42/CEE about medical devices and Directive 98/8/CE about the introduction of biocides onto the market
Legislative Decree 24/02/1997, n. 46	Application of the 93/42/CEE Directive about Medical Devices
Legislative Decree 25/01/2010, n. 35	Modifications and additions to the 20/02/97 Decree n. 46
UNI EN ISO 14971	Application of risks managing to medical devices
UNI CEI EN ISO 15223-1	Medical devices - Symbols for use in the medical device labels, labelling and information to be provided. Part 1: general requirements
UNI CEI EN 1041	Information supplied by the medical devices manufacturer
CEI EN 62366	Medical Devices - Application of the utilisation characteristics of engineering to medical devices
MEDDEV 2.4/1a-b	Guideline for the classification of medical devices
NB-MED 2.5.1/Rec 5	Technical Documentation
MEDDEV 2.7.1	Clinical Data
MEDDEV 2.12/1	Medical Devices vigilance system
UNI EN 14155	Clinical evaluation of the medical devices for human beings - Part 2: Clinical evaluation plans

3.6 Environmental conditions

Functioning temperature: from 0 to +40 °C
Storage temperature: from -20 to +50 °C
Relative humidity: from 10 to 50 %

4. OPERATING INSTRUCTIONS

4.1 Transport and storage

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks, bumps or falls during the transport itself.
Keep the original packaging for use in case of any further transport and for storage. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. The device must be stored in a dry, cool area away from direct sunlight. It must not be placed in contact with any substances or chemical agents which could cause damage and reduce safety characteristics.

4.2 Preparation

On receipt of the product:

- Remove the packaging and display the material so that all components are visible.
- Check that all the components/pieces on the accompanying list are present.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage. In particular, check:

- General functionality of the device
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Absence of cuts, holes, tears on the structure, including the straps
- Correct fixation of straps

- Correct fastening of straps
- State of use (belts, cover sheets, straps)
- Integrity of sewing and cover sheets
- Integrity of components
- **Integrity of splints (apply light pressure on the centre of the device in order to check any breakages; do not apply a flexion force higher than 12 kg)**

If the above conditions are met, the device may be considered ready for use; otherwise you must immediately remove the device from service and contact the Manufacturer.

4.3 Functioning

1. Sometimes, to apply Spencer Spine Splint, it is necessary to create space behind patient's back. To do that, immobilize first vertebral spine of patient manually until alignment position.

Fig. B

2. While two rescuers maintain this position, a third one will move ahead the patient of approximately 5 cm, applying a traction on his basin, so as to obtain enough space to insert the support to avoid bending his vertebral spine.

Fig. C

3. After that, the third rescuer will apply Spencer Spine Splint, partially closed, from the bottom upwards, placing first arm to help insertion.

Fig. D

4. Once having fixed Spencer Spine Splint, release cross belts from the top; spread them to the extricator sides and open the ventral wings behind the patient. Fix the belts starting from one of thorax ones.

Fig. E

5. To reach right position it is necessary to raise and align Spencer Spine Splint to the patient. To be sure to have reached right position, fast one of the thorax belts starting from the shoulder to opposite armpit. While locking the first belt, raise the extricator so that tension will not allow any movement. Thus final position is reached.

Fig. F

6. Spencer Spine Splint, cervical collar and fixing system to the spine board carry out symmetrical serrations so as to avoid causing damages to the patient. Once locked second thorax belt, it is necessary to check Spencer Spine Splint position.

Fig. G

7. To obtain correct position, lock the cross belts passing them under patient gluteus, limiting basin rotations and pressures over genitalia.

Fig. H

8. Once finished positioning phase, fasten ventral belts without tightening hard so as to concur to a good abdominal expansion and diaphragmatic ventilation. Now fix the head aligning it correctly, if necessary placing some suitable pillows under it.

Fig. I

9. Rescuers will provide maintaining head constantly immobilized, the chin holder and frontal band fixed to limit patient mouth opening as much as possible. Passing the chin holder under the collar and around patient jaw angle, Spencer Spine Splint action in addition to collar will maintain vertebral column alignment. Once finished fixing operations it is possible to mobilize the patient to the spine board, using it as an inclined board to reduce injured structure, solicitations.

Fig. J

10. A good co-ordinate and trained team take about 7-8 minutes to carry out these operations. It is very important to reduce supports application times and garantee a good patient positioning to avoid to expose him to further risks during extrications and transports operations.

Fig. K

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
Closure is insufficient	Closing system is worn out	Put immediately the device out of service and contact the service centre
The wooden supports inside have lost their functional characteristics	Wear and tear	

5. MAINTENANCEAND CLEANING

5.1 Cleaning

Failure to carry out the correct cleaning routine could increase the risk of cross infection, due to presence of body fluids and/or residuals.

The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.

For a correct device storage, clean it as follows. Clean by means of a clean cloth and bactericidal or germicidal disinfectant. Rinse with hot water, extend the device and leave it to dry in a parched environment free from humidity. Keep clean the outward surface by means of a clean cloth. Do note use chemical solvents.

5.2 Maintenance

5.2.1 Precautionary maintenance

The person who carries out the precautionary maintenance of the appliance (user in person, Manufacturer/supplier or a third party) has to guarantee the following basic requirements:

- Technical knowledge of the appliance and of the periodic maintenance procedures as described in these instructions.
- Specific qualifications and training in the maintenance operations of the appliance in question.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the Manufacturer to maintain post sales records and traceability of the appliance if requested.

The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.

Checks to be carried out before and after each use, and at least every 3 months, are as follows:

- General functionality of the device
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Absence of cuts, holes, tears on the structure, including the straps
- Correct fixation of straps
- Correct fastening of straps
- State of use (belts, cover sheets, straps)
- Integrity of sewing and cover sheets
- Integrity of components
- **Integrity of splints (apply light pressure on the centre of the device in order to check any breakages; do not apply a flexion force higher than 10 kg)**

The inspection frequency is determined by factors such as legal requirements, the type of use, frequency of use, environmental conditions during use and storage. Please note that you must do the cleaning as described in paragraph 5.1 and verify functionality before and after each use. Spencer Italia S.r.l. declines any responsibility for the proper functioning or damages caused to the patient or user by the use of devices not subject to routine maintenance warranty and will void the compliance to the Medical Device Directive 93/42/CEE.

The person responsible for routine maintenance must identify damaged/worn parts, but the replacement or restoration of them can only be carried out by the manufacturer or or by an authorized service centre.
For other replacement/repair activities contact the Manufacturer or an authorized centre.

Use only accessories/original spare parts approved by Spencer Italia S.r.l., otherwise we will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not been repaired, or certified on expiry date by the Manufacturer or by one of the Manufacturer's Authorised Service centres. Warranty will be considered void in compliance with the Medical Device Directive 93/42/EEC.

5.2.2 Periodic maintenance

Planned interventions by the Manufacturer or authorized center are not required, but it is prescribed to make cleaning and checking indicated in the specific sections "Cleaning" and "Precautionary Maintenance".

5.2.3 Special servicing

Only the Manufacturer or centres with written authorisation are authorised to complete any special servicing operations.

For any operations that are not carried out directly by the Manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.

The device, if used as indicated in the following instruction manual, has an average life span of 5 years.

Spencer Italia S.r.l. will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not passed the life span expected by the Manufacturer.

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

There aren't accessories available for this device.

6.2 Spare parts

SR00210A	Set of chin/fore head strap
SR00174A	Transport bag for Spencer Spine Splint adult
SR00185A	Transport bag for Spencer Spine Splint paediatric

ATTACHMENT A – TRAINING REGISTER

The product must be used only by trained personnel who have attended specific training for the use of this device and just for products with similar characteristics.

Keep this document at least 10 years after the end of life of the device.

Operator's name	Training date		Training method (user's manual, during service, former class, etc.)	Trainer
	Basic training	Advanced training		

ATTACHMENT B – MAINTENANCE REGISTER

Keep this document at least 10 years from the end of life of the device.

Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the User's Manual.

Code and description of the device	
Purchase date	
Lot (LOT) or serial number (SN)	
Bought by	

SERVICE DATE	KIND OF SERVICE (Maintenance/ check/ extension of life span)	OPERATIONS MADE ON THE DEVICE	RESULT	PERSON IN CHARGE OF SERVICE (Operator/ Authorized centre/ Manufacturer)